Family list
2 application(s) for: WO9963913 (A2)

1 **Surgical implant**

Inventor: EVANS SAMUEL LEWIN ; UPADHYAY SHANTI
Applicant: SURGICARFT LTD
EC: A61F2/30G; A61F2/44F; (+1)
IPC: *A61F2/30; A61F2/44; A61B17/86;* (+10)
Publication info: AU4158599 (A) — 1999-12-30

2 **SURGICAL IMPLANT**

Inventor: EVANS SAMUEL LEWIN [GB] ; UPADHYAY SHANTI [GB]
Applicant: SURGICARFT LTD [GB] ; EVANS SAMUEL LEWIN [GB] (+1)
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Publication info: WO9963913 (A2) — 1999-12-16
WO9963913 (A3) — 2000-02-24

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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/44

A2

(11) International Publication Number: **WO 99/63913**

(43) International Publication Date: 16 December 1999 (16.12.99)

(21) International Application Number: PCT/GB99/01778

(22) International Filing Date: 4 June 1999 (04.06.99)

(30) Priority Data:
9812103.1 5 June 1998 (05.06.98) GB

(71) Applicant *(for all designated States except US)*: SURGICRAFT LIMITED [GB/GB]; Fishing Line Road, Redditch, Worcs B97 6HF (GB).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: EVANS, Samuel, Lewin [GB/GB]; 3 Prince's Street, Roath, Cardiff CF2 3PR (GB). UPADHYAY, Shanti [GB/GB]; 25 Cog Road, Sully, Vale of Glamorgan (GB).

(74) Agents: PEARCE, Anthony, Richmond et al.; Marks & Clerk, Alpha Tower, Suffolk Street Queensway, Birmingham B1 1TT (GB).

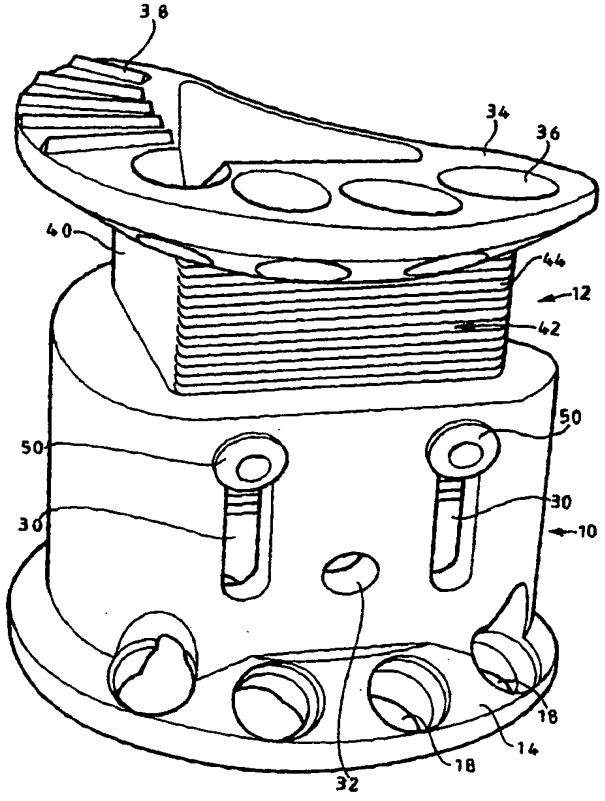
(81) Designated States: AU, JP, KR, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: SURGICAL IMPLANT

(57) Abstract

A surgical implant for insertion between a pair of adjacent vertebrae has first and second telescopic members (10 and 12) provided with vertebrae–engaging flanges (14 and 34). The members (10 and 12) have mutually engageable walls (24 and 42) provided with teeth (26 and 44) or surface roughening thereon. Fixing screws (50) pass through slots (30) in the member (10) and engage in internally screw–threaded apertures (46) on the member (14) to hold the walls (24 and 42) in mutual engagement.



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SURGICAL IMPLANT

This invention relates to a surgical implant and is more particularly concerned with a surgical implant which is adapted to be inserted between adjacent vertebrae and which is intended to contain and support a bone graft material in order to encourage the growth of new bone through and around the implant, so as to fuse the adjacent vertebrae. Such bone graft material may be bone from the vertebral body that is being replaced, or from another site such as the pelvis or a rib, or bone from another patient, or an artificial material such as calcium hydroxyapatite. Normally, this is ground to a paste and used to fill the implant.

One known form of such surgical device consists of a mesh tube and two end caps which are arranged to fit onto the tube. In use, the surgeon trims the mesh tube to length and then fits the end caps onto the ends of the tube before wedging the implant in place between a pair of adjacent vertebrae. If the mesh tube is not precisely the correct length after having been trimmed, then it has to be dispensed with and a fresh mesh tube trimmed to length. Additionally, a separate plate is required to be fitted in order to stabilize the whole assembly.

Another known type of surgical implant consists of a central tube and two end plates. The tube screws into the end plates with left and right hand threads so that the effective length of the implant can be adjusted after implantation by rotation of the tube. This type of implant also requires an additional or stabilising plate. Additionally, the screw threads are vulnerable to jamming or stripping during surgery and also limit the

strength of the implant.

It is an object of the present invention to provide an improved surgical implant in which the above disadvantages are obviated or mitigated.

According to the present invention, there is provided a surgical implant adapted to be inserted between a pair of adjacent vertebrae, said implant comprising (i) a first member having a first flange which is adapted to be secured to one of the vertebrae; (ii) a second member having a second flange which is adapted to be secured to the other of the vertebrae, the first and second members being adapted for mutual telescopic engagement so that the first and second flanges can be adjusted to a desired mutual spacing; (iii) mutually engageable first and second restraining means provided, respectively, on the first and second members, said first and second restraining means, when mutually engaged, serving to oppose movement of the first and second flanges towards one another; and (iv) fixing means for holding the first and second restraining means in mutual engagement.

Thus, with a surgical implant according to the present invention, the facility for mutual telescopic interengagement of the first and second members enables the first and second flanges to be set to the desired mutual spacing *in situ*. Once this has been done, the first and second restraining means are held in mutual engagement by the fixing means so as to hold the flanges at the desired mutual spacing. The provision of the first and second flanges enables the first and second members to be secured to the respective vertebrae, thereby avoiding the need to provide a separate stabilizing plate.

The first and second flanges may be apertured to enable fixing screws or

the like securing elements to be passed through the flanges and into the respective vertebrae.

Preferably, the first and second members are arranged so that, when they are mutually telescopically interengaged, a limited amount of lateral movement relative to the direction of telescope movement is permitted whereby to enable the first and second restraining means to be mutually engaged or disengaged as desired.

In one embodiment, each of the first and second restraining means comprises a row of teeth provided on the respective member and extending away from the respective flange. Conveniently, each tooth has an abutment surface which extends substantially perpendicularly to the direction of telescopic movement of the members in such a way that engagement of the abutment surfaces of at least some of the teeth of one row with corresponding abutment surfaces of at least some of the teeth of the other row prevents movement of the first and second flanges towards one another.

In another embodiment, the first and second restraining means comprise a roughened surfaces on the respective first and second members, the roughened surfaces extending the direction of telescopic movement of the members and being mutually engageable. The roughening on the surfaces may be formed by grit-blasting or any other convenient surface roughening procedure or may be formed at the time of forming the surfaces themselves.

Surfaces of the flanges which are adapted to abut against the respective vertebrae may be provided with projections which are designed to bite into the surface of the vertebrae to improve the security of the joint

between the flanges and the vertebrae.

Most preferably, the first member, the first flange and the first restraining means are of one-piece construction. Likewise, the second member, the second flange and the second restraining means are most preferably also of one-piece construction.

The fixing means for retaining the first and second restraining means in their mutually interengaged relationship may comprise at least one fixing screw having a screw-threaded shank passing through a slot in one of the first and second members and engaging in an internally screw threaded bore in the other of the first and second members.

An embodiment of the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:-

Fig 1 is a perspective view of one example of surgical implant according to the present invention,
Fig 2 is a side elevation of a first member forming part of the implant of Fig 1,
Fig 3 is a section on the line A-A of Fig 2,
Fig 4 is a plan view of the member of Figs 2 and 3,
Fig 5 is a side elevation of a second member forming part of the implant of Fig 1,
Fig 6 is a section on the line A-A of Fig 5, and
Fig 7 is a top plan view of the second member of Figs 5 and 6.

Referring now to the drawings, the surgical implant is for implantation between a pair of adjacent vertebrae (not shown). The implant comprises a first member indicated generally by arrow 10 and a second member

indicated generally by arrow 12. Each of the members 10 and 12 is of one-piece construction and is formed of a titanium alloy such as Ti-6Al-4V.

Referring now particularly to Figs 2 to 4, the first member 10 has a first flange 14 at one end thereof. The first flange 14 has a multiplicity of apertures 18 therethrough to receive vertebral fixing screws (not shown) to enable the first member 10 to be secured to one of the adjacent vertebrae. These apertures 18 have part-spherical regions 18a for engagement by part-spherical regions on the heads of the fixing screws to permit the latter to point in directions considered appropriate by the surgeon. As can be seen from Fig. 4, the cross-sectional shape of the first member 10 and first flange 14 corresponds to the shape of that portion of the vertebra to which it is to be secured. The first member 10 has a passage 20 extending therethrough from one end to the other. As can be seen from Fig. 4, the passage 20 is of generally right-triangular cross-section, but with a side corresponding to the "hypotenuse" of the triangle being of complex curved shape to follow the shape of the adjacent external surface of the first member 10. The passage 20 has a substantially planar, smooth wall 22 and a substantially planar wall 24 formed with teeth 26 extending completely across the wall 24. The teeth 26 are arranged in a row extending axially of the passage 20 from the flange-remote end of the first member 10 towards but not completely up to the flange 14.

The end surface of the flange 14 which is to engage against the respective vertebra is provided with a series of projecting ribs 28 in a region thereof adjacent to the wall 22 of the passage 20. The stepped apertures 18 are provided through a region of the flange 14 adjacent to the wall 24 bearing the teeth 26.

The first member 10 has a pair of mutually parallel, axially extending slots 30 extending from the external surface thereof to the passage 20, such slots 30 opening into the passage 20 via the wall 24 bearing the teeth 26. A circular aperture 32 is provided between the slots 30 and in this embodiment is internally screw-threaded to enable a handle to be removably attached for facilitating insertion of the device.

Referring now particularly to Figs. 5 to 7, the second member 12 has a second flange 34 at one end thereof. The second flange 34 has a multiplicity of apertures 36 therethrough to receive fixing screws (not shown) to enable the second member 12 to be secured to the other of the pair of adjacent vertebrae. The apertures 36 are formed with part-spherical regions 36a and serve the same purpose as the regions 18a. The shape of the second flange 34 is similar to that of the first flange 14 and is likewise provided with projecting ribs 38 in a region of its surface destined to engage with a surface of the vertebra to which it is to be secured.

As can be seen particularly from Fig. 7, a hollow main body portion 40 of the second member 12 has a cross-sectional shape corresponding to that of the passage 20 but with smaller dimensions so that the main body portion 40 is telescopically engageable in the passage 20 of the first member 10. In a like manner to the wall 24, an external wall 42 of the main body portion 40 has teeth 44 extending completely across the wall 42. The teeth 44 are arranged in a row extending longitudinally of the main body portion 40. The teeth 44 are shaped so as to provide abutment surfaces which extend perpendicularly to the longitudinal axis of the main body portion 40 and which face away from the second flange 34. Likewise, the teeth 26 of the first member 10 have abutment surfaces which extend perpendicularly with respect to the longitudinal axis of the first member 10 and which face away from the first flange 14.

The main body portion 40 is hollow so as to enable it to be packed with bone graft material.

The external shape of the main body portion 40 of the second member 12 is dimensioned so that, when the second member 12 is telescopically engaged in the passage 20 of the first member 10, a small amount of lateral movement of the main body portion 40 within the passage 20 is permitted to enable the teeth 44 to be engaged with or disengaged from the teeth 26. It will be appreciated that, when the teeth 26 and 44 are in mutual engagement, the first and second members 10 and 12 will be held against relative movement in a direction which reduces the spacing between the first and second flanges 14 and 34.

The main body portion 40 has a pair of laterally spaced internally screw-threaded apertures 46 therethrough which are laterally spaced by a distance corresponding to the lateral spacing of the slots 30 in the first member 10. The apertures 46 are located part way along the row of teeth 44. A slot 48 is provided through the wall of the main body portion 40 and extends from the end of the latter remote from the flange 34 to terminate beyond a line joining the apertures 46. The slot 48 is aligned with the aperture 32 in the assembled implant.

The surgical implant further comprises a pair of fixing screws 50 having shanks which can be passed through the slots 30 and engaged in the internally screw-threaded apertures 46. It will therefore be understood that the first and second members 10 and 12 can be telescopically adjusted to the desired mutual spacing between the first and second flanges 14 and 34, and then the fixing screws 50 can be tightened so as to bring the teeth 44 and 26 into mutual engagement whereby to lock the assembly in position.

The surgical implant can be produced in a range of sizes to enable a surgeon to select an appropriate size having regard to the anatomy of the patient being fitted with the implant. The number of teeth 26 and 44 can be chosen to give the required accuracy of setting of the spacing between the flanges 14 and 34. In this particular embodiment, there are twenty teeth 26 and twenty teeth 44.

The previously described handle has a screw-threaded shank engageable with the aperture 32 and a pair of laterally extending protrusions which are designed to engage against the heads of the screws 50 so as to hold them against the body of the first member 10 and thereby retain the teeth 44 and 26 in a position in which they are not mutually interengaged.

In use, the surgeon prepares the site in the region of the pair of vertebrae between which the implant is to be fitted. After this, the surgeon inserts the implant using the handle with the fixing screws 50 loosened and the first and second members 10 and 12 telescoped inwardly so that the flanges 14 and 34 are at a minimum spacing. The hollow body portion 40 of the second member has previously been packed with bone graft material. The surgeon telescopically expands the implant until the first and second flanges 14 and 34 are engaged with the respective surfaces of the vertebrae. The handle is removed and the fixing screws 50 are tightened so as to draw the teeth 26 and 44 into firm mutual interengagement to prevent telescopic collapsing of the first and second members 10 and 12. Following this, vertebral fixing screws (not shown) are passed into the apertures 18 and 36 in the respective flanges 14 and 34 and engaged in the respective vertebrae at the required angles so as to hold the implant in position.

Further bone graft material may be packed into the implant through the aperture 32 and recess 48 aligned therewith.

In an alternative procedure, the surgeon may overextend the members 10 and 12, pack it full of bone graft material and then shorten it slightly to compress the bone graft material against the adjacent vertebrae. There are a number of ways of making use of the hole 32 to pack in additional bone graft material after the members 10 and 12 have been extended. This may or may not be followed by shortening slightly to compact the bone graft material. Thus, the above-described implant permits the surgeon to adopt a wide variety of possible procedures.

In an alternative embodiment, the implant is the same as that described above with reference to Figs. 1 to 7 except that, in the place of the sets of teeth 26 and 42, the corresponding mutually engageable surfaces of the walls 24 and 42 are subjected to grit blasting so as to provide surface roughnesses which oppose telescopic movement of the members 10 and 12 when held in mutual engagement by the fixing screws 50.

CLAIMS

1. A surgical implant adapted to be inserted between a pair of adjacent vertebrae, said implant comprising (i) a first member (10) having a first flange (14) which is adapted to be secured to one of the vertebrae; (ii) a second member (12) having a second flange (34) which is adapted to be secured to the other of the vertebrae, the first and second members (10,12) being adapted for mutual telescopic engagement so that the first and second flanges (14,34) can be adjusted to a desired mutual spacing; (iii) mutually engageable first and second restraining means (26,44) provided, respectively, on the first and second members (10,12), said first and second restraining means (26,44), when mutually engaged, serving to oppose movement of the first and second flanges (14,34) towards one another; and (iv) fixing means (50) for holding the first and second restraining means (26,44) in mutual engagement.

2. A surgical implant as claimed in claim 1, wherein the first and second flanges (14,34) have apertures (18,36) to enable fixing screws or other securing elements to be passed through the flanges (14,34) and into the respective vertebrae.

3. A surgical implant as claimed in claim 1 or 2, wherein the first and second members (10,12) are arranged so that, when they are mutually telescopically interengaged, a limited amount of lateral movement relative to the direction of telescope movement is permitted whereby to enable the first and second restraining means (26,42) to be mutually engaged or disengaged as desired.

4. A surgical implant as claimed in any preceding claim, wherein each of the first and second restraining means comprises a row of teeth (26

or 42) provided on the respective member (10,12) and extending away from the respective flange (14,34).

5. A surgical implant as claimed in any one of claims 1 to 3, wherein the first and second restraining means (26,42) comprise roughened surfaces on the respective first and second members, the roughened surfaces extending the direction of telescopic movement of the members and being mutually engageable.

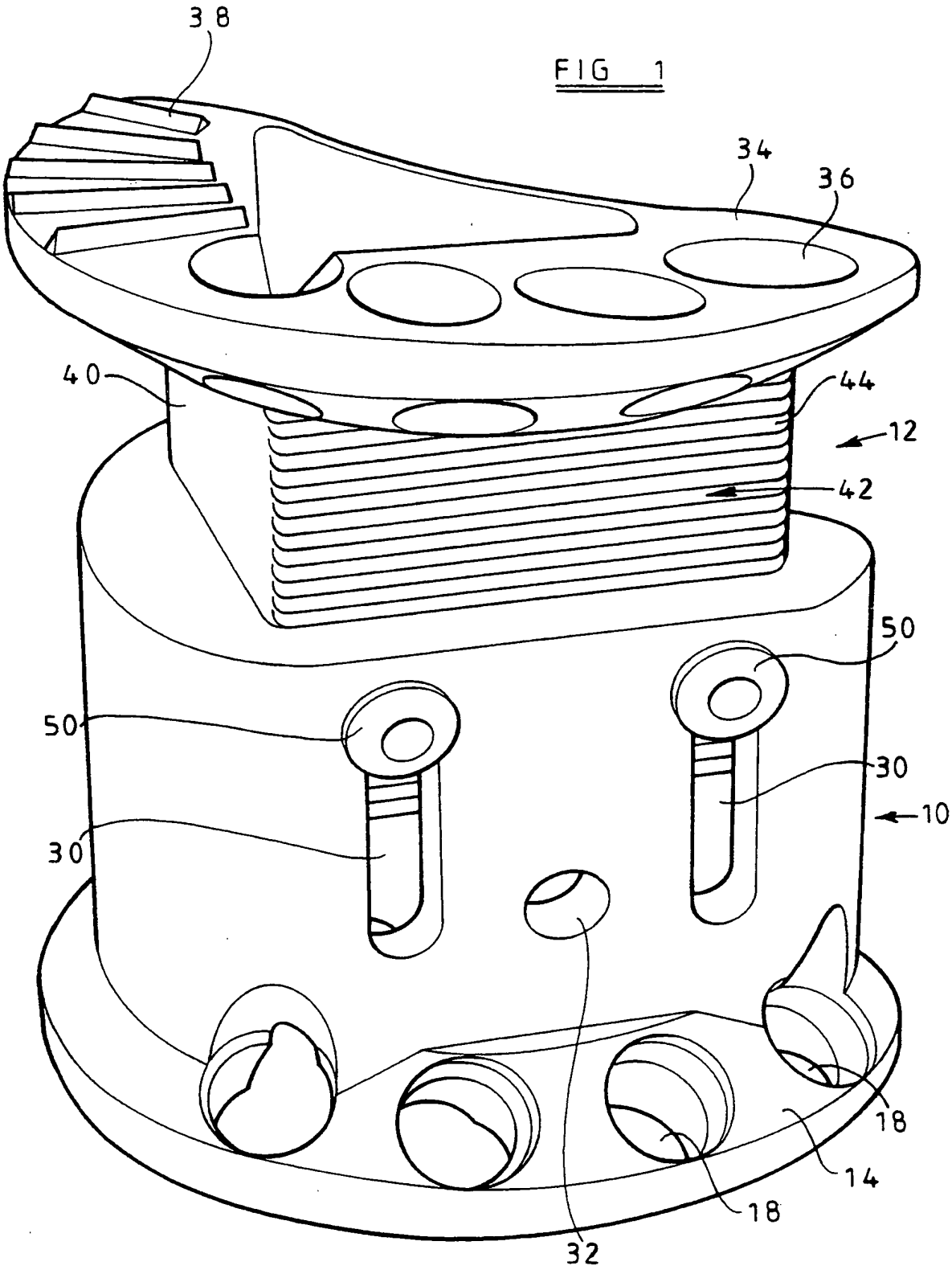
6. A surgical implant as claimed in any preceding claim, wherein surfaces of the flanges (14,34) which are adapted to abut against the respective vertebrae are provided with projections (38) which are designed to bite into the surface of the vertebrae to improve the security of the joint between the flanges (14,34) and the vertebrae.

7. A surgical implant as claimed in any preceding claim, wherein the first member (10), the first flange (14) and the first restraining means (26) are of one-piece construction.

8. A surgical implant as claimed in any preceding claim, wherein the second member (12), the second flange (34) and the second restraining means (44) are of one-piece construction.

9. A surgical implant as claimed in any preceding claim, wherein the fixing means (50) for retaining the first and second restraining means (26,42) in their mutually interengaged relationship comprise at least one fixing screw having a screw-threaded shank passing through a slot (30) in one of the first and second members (10,12) and engaging in an internally screw threaded bore (46) in the other of the first and second members (10,12).

FIG 1



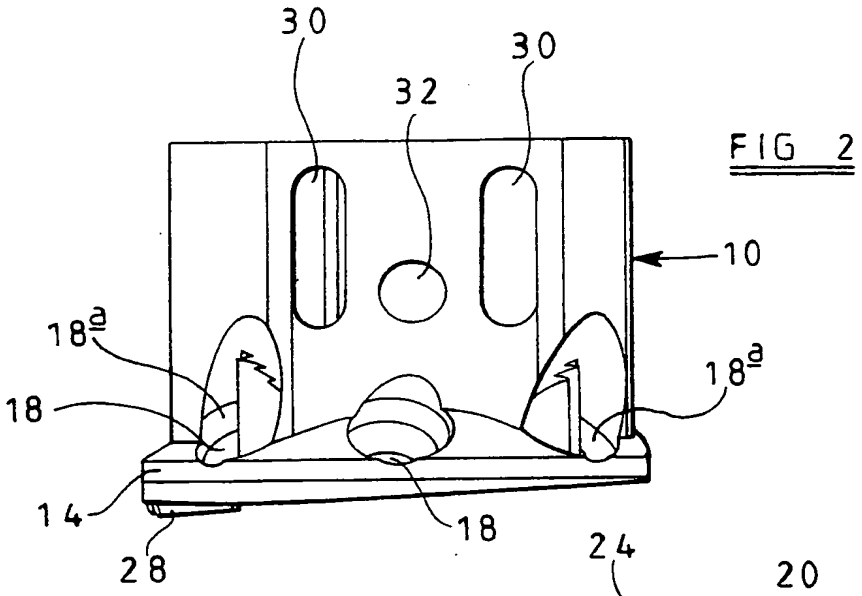


FIG 2

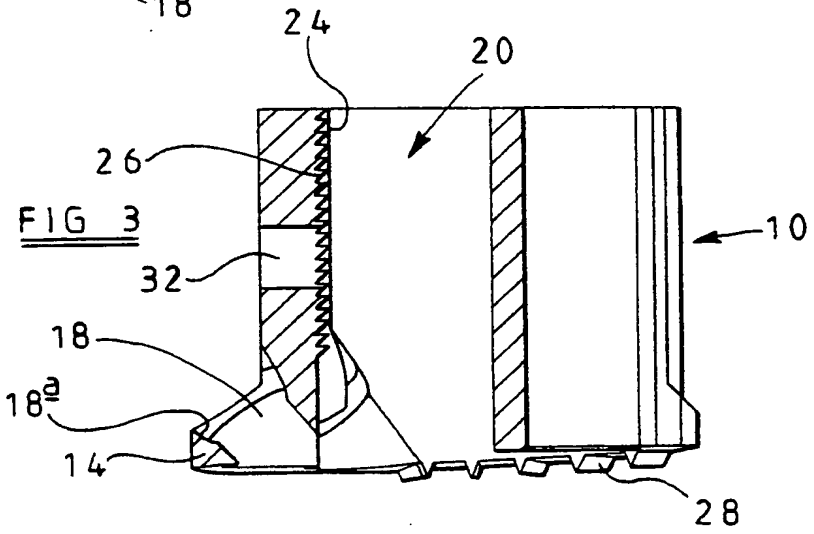


FIG 3

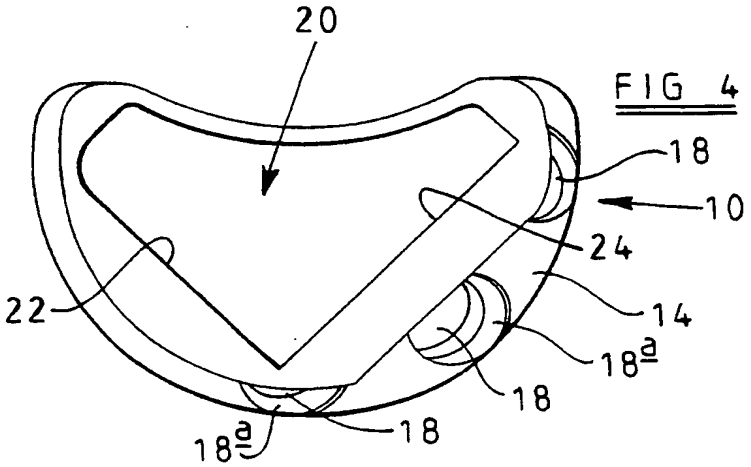


FIG 4

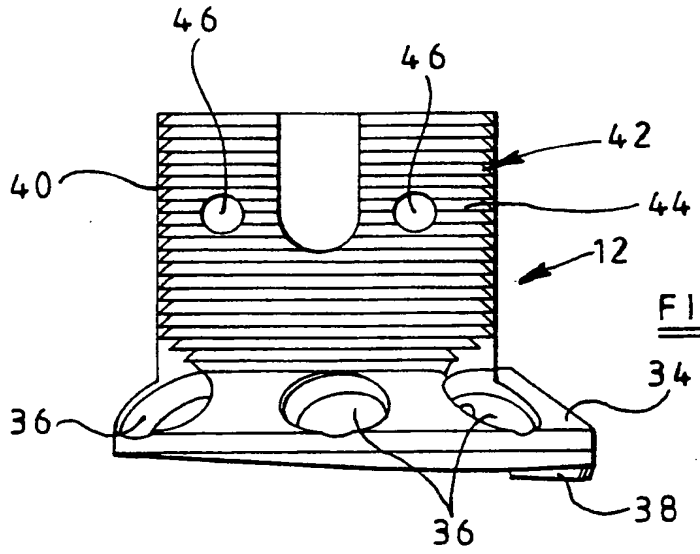


FIG 5

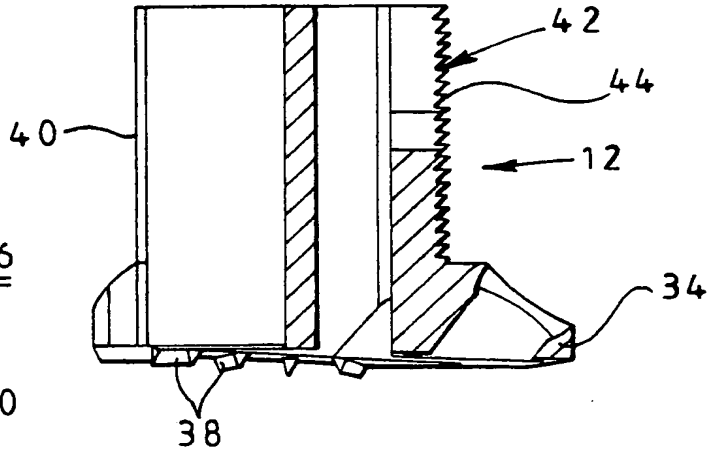


FIG 6

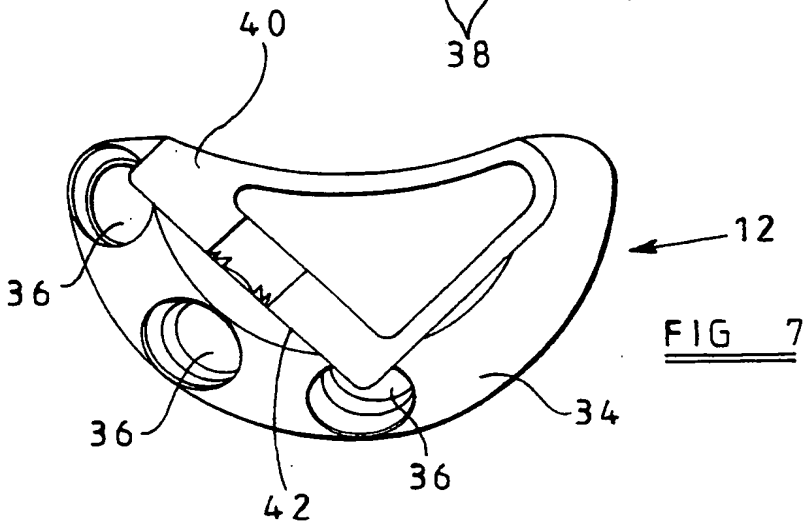


FIG 7